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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
Nashville Branch Office
Plus Park Blvd.
Nashville, TN 37217

Tel: 615-781-5388
FAX: 615-781-5383

May 22, 2003

VIA FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. John F. Turner, Owner, Manager
Millstone Agri Distributors
3721 E. Lamar Alexander Highway
Maryville, TN 37804

Warning Letter No 03-NSV-16

Dear Mr. Turner:

An inspection of your animal feed manufacturing operation, located at Maryville, Tennessee conducted by a U.S. Food and Drug Administration investigator on February 13, 2003, found significant deviations from the requirements set forth in Title 21, *Code of Federal Regulations* (21 C.F.R.), Part 589.2000 - Animal Proteins Prohibited in Ruminant Feed. The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Because you failed to follow this rule, products you manufactured and distributed are adulterated within the meaning of Sections 402(a)(2)(C) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) since they contain an unsafe food additive and were "prepared, packed, or held under insanitary conditions . . . whereby [they] may have been rendered injurious to health." Feed you manufactured also was misbranded within the meaning of Section 403(a)(1) of the Act because of your failure to follow this rule.

Our investigation found the following violations of 21 C.F.R. 589.2000:

1. Failure to separate the receipt, processing, and storage of products containing prohibited material from products not containing prohibited material [21 C.F.R. 589.2000(e)(1)(iv)];

2. Failure to establish written procedures, including clean-out and flushing procedures, to avoid commingling and cross-contamination of common equipment [21 C.F.R. 589.2000(e)(1)(iii)(B)];

3. Failure to maintain records sufficient to track prohibited materials throughout the receipt, processing, and distribution of your products [21 C.F.R. 589.2000(c)(1)(ii)];

4. Failure to provide for measures to avoid commingling or cross-contamination of feeds intended for ruminants and feeds intended for nonruminants that may contain prohibited materials [21 C.F.R. 589.2000(c)(1)(iii)]. Specifically, our investigation found that the ruminant product "10% Beef Conditioner" was formulated primarily with screenings and fines derived from previously manufactured non-ruminant products, "Premium Rooster Kicker" in particular, that contain or may contain prohibited material. Such deviations cause the ruminant product "10% Beef Conditioner" being manufactured at this facility to be adulterated within the meaning of Sections 402(a)(2)(C) and 402(a)(4) of the Act;

5. Failure to label your non-ruminant products with the required cautionary statement "Do not Feed to Cattle or Other Ruminants" [21 C.F.R. 589.2000(c)(1)(ii)]. Our investigation specifically found that dog food containing prohibited material was added as an ingredient to your product "Premium Rooster Kicker." The failure of these feeds to bear the required BSE warning statement causes them to be misbranded within the meaning of Section 403(f) of the Act.

The above is not intended to be an all-inclusive list of deviations from the regulations. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulations.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper
Director, New Orleans District Office

Enclosure: Small Entity Compliance Guide

cc: Anthony C. Curtis, Owner